

Challenges and Opportunities in Product Development

An Overview from 30,000 ft.

(No data)

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Building a Development Plan

What is the indicated use of the product?

What is the safety profile of the product?

What is (are) the mechanism(s) of action of the product?

Who is going to do the studies?

WHAT ABOUT THE ANIMAL STUDIES?

Mouse, guinea pig, rabbit prior to non-human primate?

Which non-human primate? Indian rhesus, Chinese rhesus, Cynomolgus, African green, Marmoset?

**Characterization of the Disease:
Is the animal model similar to human?**



The flowchart is set against a dark blue background with two vertical white dashed lines. It depicts a sequence of steps in drug development, each represented by a light blue arrow pointing right. The steps are: 'Pre-Clin Safety' and 'Scale-up Mfg' (both in the first column), 'Ph I IND Study' (spanning the first and second columns), 'GLP Animal Challenges (Pivotal)' (spanning the second and third columns), and 'Expanded human studies' (spanning the third and fourth columns). A red triangle points up to 'Pre-IND Mtg' in the first column and another points down to 'Approval' in the fourth column. The date '10-11Jun04' is in the bottom left.

Pre-Clin Safety

Scale-up Mfg

Ph I IND Study

**GLP Animal
Challenges (Pivotal)**

**Expanded human
studies**



Pre-IND Mtg



Approval

10-11Jun04

The Bottleneck

The challenge studies must include:

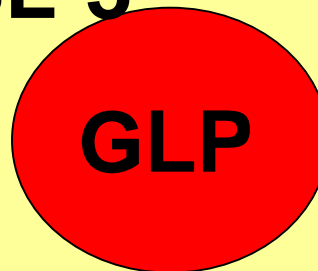
- 1. BSL-3 or 4 compliance**
- 2. Aerosol exposure to non-human primates (in one study)**
- 3. Full GLP documentation**

Conducting “Animal Rule” Studies

Aerosol challenge

non-human primates

BSL-3



USAMRIID, Battelle, Lovelace (05?)

Personnel

Vaccinations?

Clearance for select agent use?

**Trained with non-human primates, GLP
documentation, BSL-3 techniques?**

What about the clinical trials?

Who will do them?

Who will pay for them?

FINANCING: Grants and Contracts

“Government Alphabet Soup”

NIH (NIAID): original, innovative basic research - getting into advanced development and clinical trials (Peer review system?)

DTRA: Defense Threat Reduction Agency
Basic Research and Initial development of products
beyond proof of concept – military relevance

FINANCING:

Grants and Contracts (Cont'd)

USAMRMC: U.S. Army Medical Research and Materiel Command, Ft. Detrick
Military relevant research: contracts; CRADAs with USAMRIID, WRAIR; contracts for clinical trials

DARPA: Defense Advanced Research Products Agency
Contracts for really innovative product discovery areas focused on military applications
New to biology—previously physics and engineering

FINANCING:

Grants and Contracts (Cont'd)

BioShield: Product acquisition and stockpiling for public health

-- A DHHS agency

“Fully burdened costs”



Funding

**Initial funding
to support the
bright light of
discovery**

**The
Valley of
Product
Death**

**Marketing
and
Government
Acquisition**

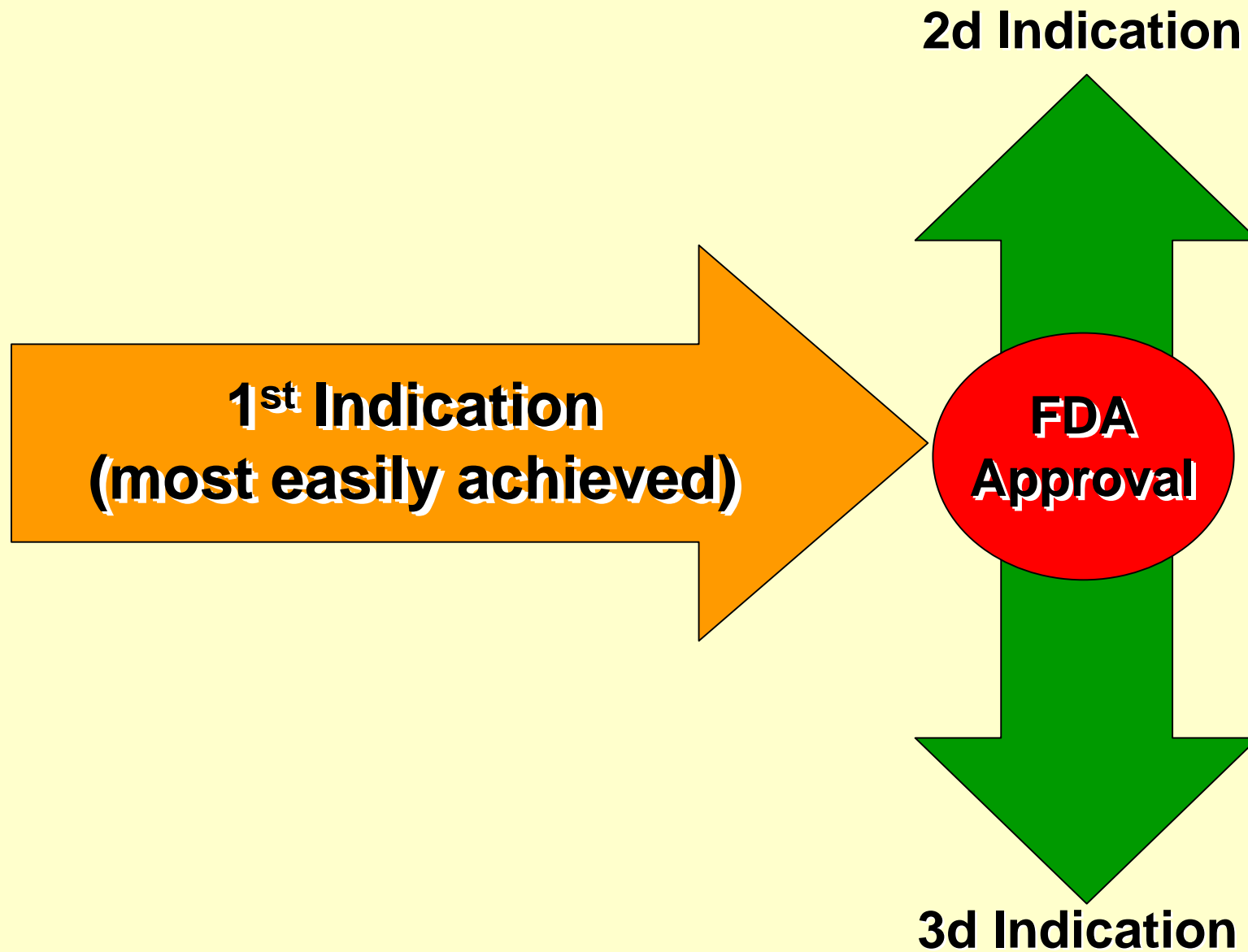
**Rickety bridge over the
Valley of Death
(Outside funding, VCs?)**

**Start-up
Agency**

**Government
Acquisition**

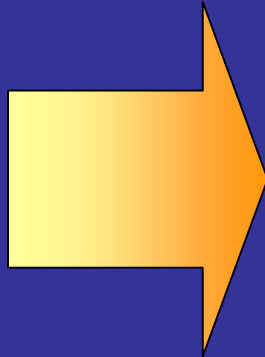
**NIH?
DARPA?
DTRA?**

**BioShield?
Marketplace?**



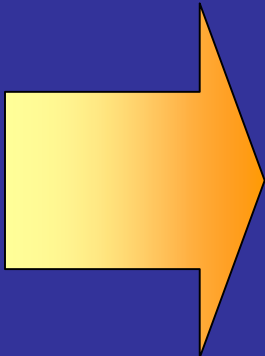
Goals

**Company
Goals**



Make Money
Help the Country?

**Government
goals**



**Have the product
available when
needed**

**Avoid having to develop
the product internally**

Critical Questions

What is your incentive for getting in this business?

Can you find an indication that will make money?

What is the government restock rate?

Critical Questions (Cont'd)

How many products is the government willing to stockpile?

BioShield now approved. How do you survive the “fully burdened cost structure?”

What is the indemnification profile of your product?

Where to get help?

**Program Staffs and Web Sites of
NIAID, DTRA, DARPA**

**FDA Web Site and Pre-IND meetings
(once you have a product)**